

TABLE OF CONTENTS	PAGE
1.0 INTRODUCTION	4
2.0 STUDY OBJECTIVES	6
3.0 INSTITUTIONAL REVIEW BOARD	7
4.0 INFORMED CONSENT	7
5.0 STUDY POPULATION	7
5.1 Inclusion Criteria	7
5.2 Exclusion Criteria	7
6.0 STUDY PLAN	8
6.1 Design	8
6.2 Recordkeeping and Monitoring	9
6.3 Investigational Supplies	9
6.3.1 Study Drug Description	9
6.3.2 Packaging	9
6.3.3 Dosage Preparation	10
6.3.4 Dose Administration	11
6.3.5 Storage Requirements	11
6.3.6 Study Drug Accountability	11
6.3.7 Retrieval and Destruction	11
6.4 Randomization and Blinding	11
6.5 Methods	12
6.5.1 Screening Visit #1 (21 to 17 days before Day 0)	12
6.5.2 Screening Visit #2 (minimum 4 days after Screening Visit #1)	13
6.5.3 Day 0 (Randomization and Immunization)	13
6.5.4 Day 7 (± 3 days)	14
6.5.5 Day 42 (± 7 days)	15
6.5.6 Day 182 (± 14 days)	15
6.5.7 Day 378 (± 14 days)	15
6.5.8 Quarterly Visits after Day 378 (± 7 Days: Day 469, 560, 651, 743, 833, etc., until the study is closed.)	15
6.6 Laboratory Tests	15
6.6.1 Clinical Laboratory Evaluations	15
6.6.1.1 Serum Chemistry	15
6.6.1.2 Microbiology	16
6.6.2 Special Serologies (to be performed by Nabi-Rockville laboratory)	16
6.7 Study Measurements	16
6.7.1 Reactogenicity Assessment	16
6.7.2 Physical Examination	16
6.7.3 Measurement of Vital Signs	17

6.7.4 Bacteremia	17
6.7.5 Other Serious Bacterial Infections	17
7.0 ADVERSE EVENTS	18
7.1 Adverse Event Recording	18
7.2 Serious Adverse Events	19
8.0 ANALYSIS PLAN	20
8.1 Sample Size	20
8.2 Efficacy Analysis	22
8.3 Assessing Variation Among Study Sites	23
8.4 Description of S. aureus type 5 and type 8 CPS specific Antibody Levels	24
8.5 Serologic correlates of protection	24
8.6 Interim Analysis	25
8.7 Safety Analyses	25
9.0 WITHDRAWAL FROM STUDY	26
10.0 AGREEMENT WITH PROTOCOL	27
11.0 REFERENCES	28
APPENDIX A - TIME AND EVENTS SCHEDULE	31
APPENDIX B - KARNOFSKY PERFORMANCE SCALE	32
APPENDIX C - METHOD FOR NASAL CULTURE	33
APPENDIX D - VACCINE REACTOGENICITY DEFINITIONS AND REACTOGENICITY WORKSHEET	34
APPENDIX E - HOW TO TAKE YOUR TEMPERATURE	35

6.0 STUDY PLAN

6.1 Design

This is a Phase III, multicenter, prospective, randomized, stratified, placebo-controlled, double-blind clinical trial

The subjects at each site will be randomized at a 1:1 ratio to one of two treatment regimens (*S aureus* vaccine or an inactive placebo)

After injection, subjects will be observed for vaccine immunogenicity (serum *S. aureus* types 5 and 8-specific IgG) and occurrence of all culture-proven *S. aureus* infections and all culture-proven *S. aureus* bacteremias until the study is closed.

active elicitation of adverse events by history and physical examination, with assessment of seriousness and relationship to the study drug, will be carried out by the sub-investigators.

6.4 *Randomization and Blinding*

Subjects will be randomized to the two treatment groups in a 1:1 ratio.

Identical-appearing vaccine and phosphate-buffered saline placebo vials will receive blinded labeling, with each vial bearing a unique numeric code,

The assignment of unique numeric codes to active vaccine or placebo will be securely retained until such times as designated by the analysis plan (section 8.0).